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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,263	07/12/2001	Mary Ellen Rybak	OC01000KQ	3021

24265 7590 05/20/2003

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,263	RYBAK ET AL.	
	Examin r	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,9-17 and 21-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9-17,21-40 and 307* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The amendment filed February 26, 2003 is acknowledged. Claims 2, 8 and 18-20 were canceled. Claims 21-40 were added.

Claims 1, 3-7, 9-17 and 21-40 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

3. References AW, BQ and CM have been considered. A copy of the initialed and signed 1449 is attached.

Claim Rejections Withdrawn:

4. The rejection of claim 8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of its cancellation.

Claim Rejections Maintained:

5. The rejection of claims 1, 3-7, 9, 11, 12, and 14-17 under 35 U.S.C. 103(a) as being unpatentable over Kirkwood et al (Kirkwood, J.M. et al., J. Clinical Oncol. 14(1): 7-17, 1996; cited in the IDS) in view of Gilbert et al (U.S. 5,951,974; issued Sep. 14, 1999; filed Dec. 19,

1997; cited in the IDS), in view of Glue et al (U.S. 5,908,621; issued June 1, 1999; filed Apr. 29, 1997; cited in the IDS), and further in view of Talpaz et al (Blood, 92(10): 1998, page 251a; cited in the IDS) is maintained for the reasons of record and applied to new claims 21-40.

As currently amended claims 1, 3-7, 9, 11, 12, 14-17 and 21-40 are drawn to methods of treating patients having melanoma with pegylated interferon alpha, or interferon alpha-2b, wherein the pegylated interferon alpha is administered within specific dose ranges or at specific dosages. Applicant argues that none of the cited references teach the specific dose ranges or dosages, and that it would not be obvious for one of skill in the art to arrive at the claimed dose ranges or specific dosages, because the art is unpredictable. Applicant further argues that the courts have held that the recitation of specific amounts in a method may render a claimed invention unobvious over the prior art if the prior art teaches that the art is unpredictable. Applicant cites In re Sebek (175 USPQ 93, 95 (CCPA 1972)).

Applicant's arguments fail to persuade. Either of Gilbert and Glue teaches that methods for arriving at optimal dosages of pegylated interferon alpha are known in the art (see Glue, col. 6, lines 37-47; Gilbert, col. 11, lines 33-41). Furthermore, the ranges taught by Glue (0.25-2.5 microgram/kg) overlaps with the ranges recited in the broadest claims (about 3 micrograms/kg to 9.0 micrograms/kg), because 2.5 may be considered to be within the range of "about 3". While applicant has asserted that the art of arriving at optimum doses of pegylated interferon alpha is unpredictable, applicant has failed to substantiate this claim. Thus, the instant case is distinguished from In re Sebek where the court took into consideration teachings in the prior art taught indicating that the in the particular technology of In re Sebek the determination of optimum values was unpredictable: "we think that logic and reason compel the conclusion that in an area of technology shown to be highly unpredictable in process values, the discovery of optimum values not in any way suggested by the prior art is more likely to be unobvious than obvious within the meaning of § 103."

9. The rejection of claims 1, 3-7, 10, 11, 13, and 14 under 35 U.S.C. 103(a) as being unpatentable over Creagan et al (Creagan et al., J. Clinical Oncol. 13(11): 2776-2783, 1995) in view of Gilbert et al (U.S. 5,951,974; issued Sep. 14, 1999; filed Dec. 19, 1997), and further in view of Glue et al (U.S. 5,908,621; issued June 1, 1999; filed Apr. 29, 1997) is maintained for the reasons of record.

Claims 1, 3-7, 10, 11, 13, and 14 are drawn to methods of treating patients with a surgically removed melanoma comprising administering pegylated interferon alpha or interferon alpha-2a, wherein the pegylated interferon alpha is administered within specific dose ranges or at specific dosages. Applicant argues that none of the cited references teach the specific dose ranges or dosages, and that it would not be obvious for one of skill in the art to arrive at the claimed dose ranges or specific dosages, and that the art of record fails to provide a reasonable expectation of success in achieving the claimed inventions.

Applicant's arguments fail to persuade, because applicant fails to provide evidence that the art of determining dosages of pegylated interferon alpha is unpredictable. Furthermore, applicant asserts that the prior art fails to provide the reasonable expectation of success for the treatment of melanoma. This is unpersuasive because Gilbert teaches that interferon alpha conjugates may be used to treat interferon-susceptible conditions (col. 9, line 67- col. 10, line 1) and lists exemplary conditions, including that of malignant melanoma (col. 10, lines 20-26).

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
May 17, 2003

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